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10/005,290	12/04/2001	Mark Dinsmore	PHLL-154	6794

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EXAMINER
KIKNADZE, IRAKLI

ART UNIT	PAPER NUMBER
2882	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,290	Applicant(s) DINSMORE, MARK	
	Examiner Irakli Kiknadze	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation " said optic cable " in line 2.

Claim 9 recites the limitation " said fiber optical element " in line 3.

There is insufficient antecedent basis for these limitations in the claims 7 and 9.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-18 and 24-37 are rejected under 35 U.S.C. 102(e) as being antisipated by Shinar et al. (US Patent 6,320,935 B1).

With respect to claim 1 and 24 Shinan shows (Figs.1-3) a therapeutic radiation source (10), comprising: a probe assembly including an optical delivery structure (16) having a proximal end and a distal end, the optical delivery structure (16) being adapted for transmitting optical radiation incident on the proximal end to the distal end; an optical source (38), including means for generating a beam of optical radiation directed to the proximal end of said optical delivery structure;

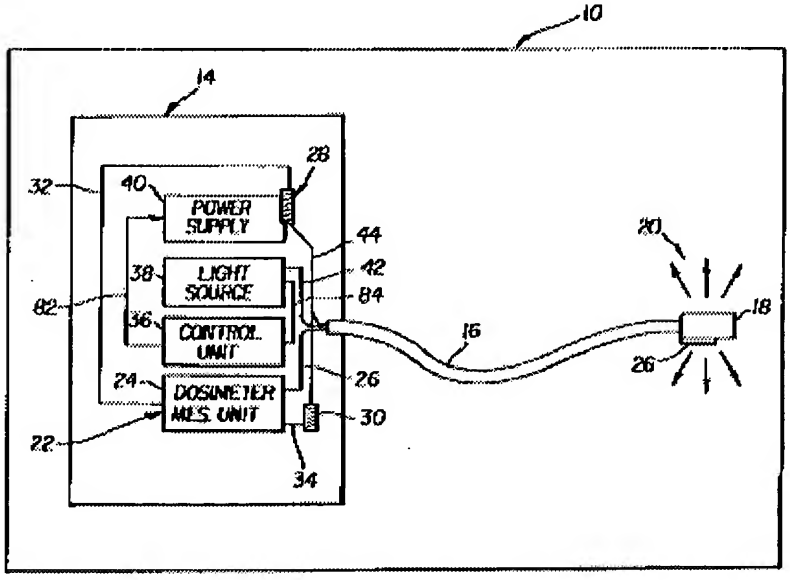


FIG. 1

a radiation generator assembly (18) coupled to the probe assembly, including: an electron source (52), responsive to light transmitted to the distal end of the optical delivery structure, for emitting electrons;

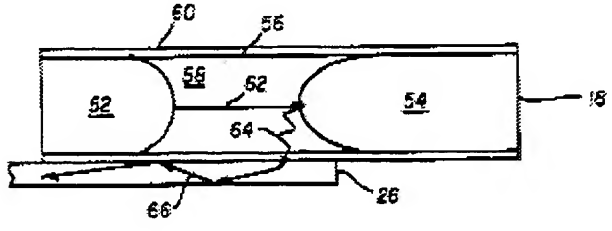


FIG. 3

and a target clement (54) including at least one radiation emissive material adapted to emit therapeutic radiation (20) in response to incident

electrons from the electron beam (62); means (40) for providing an accelerating voltage between the electron source (52) and the target element (54) so as to establish an accelerating electric field which acts to accelerate electrons (62) emitted from the electron source (52) toward the target element (54); and (see abstract) an in situ radiation detecting system (22) for monitoring an amount of the therapeutic radiation (20) emitted by the target element (54), the radiation detecting system (22) including: a scintillator (26) disposed along a path of the therapeutic radiation (64 as part of 20) emitted by the target element (54) and adapted to generate scintillator light (66) in response to the therapeutic radiation incident (64) thereon, wherein the intensity of the scintillator light (66) is proportional to the intensity of the incident therapeutic radiation (64); a photodetector (46) in optical communication with the scintillator (26) for converting the scintillator light (66) into a signal indicative of the intensity of the incident therapeutic radiation (64) (column 5; line 57 – column 8; line 58).

With respect to claims 2 and 16-18, Shinar teaches a feedback controller responsive to the indicative signal, the feedback controller including: a controller including processing means for calculating a cumulative dosage (24) of the therapeutic radiation, and control means for controlling the intensity and duration of the emitted therapeutic radiation; and feedback circuit (14) for feeding back the indicative signal to the controller (Fig.1). Further, the control means comprises intensity control circuitry for controlling the intensity of the emitted therapeutic radiation, and duration control circuitry for controlling the duration of the emitted therapeutic radiation. The duration control circuitry comprises means for selectively activating the optical source (38) (column 4; lines 45-67).

With respect to claims 3, 4 and 36, Shinar teaches that the feedback controller includes a display unit (50), so as to allow real time visual monitoring of the therapeutic radiation (Fig. 2; column 6; line 63 – column 7; line 12). The therapeutic radiation includes X-rays (column 5; lines 47-56).

With respect to claims 5,6 and 33 Shinar teaches that optical source is a laser (column 3; lines 40-60).

With respect to claims 8 and 34, Shinar teaches that radiation detection system further includes an optical system for selectively directing light so that only the scintillator light is incident upon the photodetector (46), the optical system being adapted for separating the scintollator light (66) from ambient visible light and from optical radiation generated by the optical source (38). The optical system includes an absorber material (column 7; lines 2-12).

With respect to claims 10-12, Shinar teaches that the optical delivery structure is a fiber optic cable and the probe assembly comprises an electrically conductive, flexible, outer sheath enclosing the optical delivery structure (column 3; lines 26-28). The photodetector comprises a photomultiplier tube (Fig.2).

With respect to claims 13 and14, Shinar teaches that the electrons incident on the target element (54) from the electron source (52) are accelerated by the electric field to energies in the approximate range of 10 keV to 20 keV (column 9; lines 43-45).

With respect to claims 25 and 26, Shinar teaches that the radiation generator assembly further comprises a capsule enclosing the electron source (52) and the target element (54) and defining a substantially evacuated interior region extending along a beam axis (Fig.3) The means for providing an accelerating voltage comprises a high voltage power supply (column 9; table 1).

With respect to claims 31 and 32, Shinar teaches (see abstract) a therapeutic radiation source, (Figs. 1-3) comprising: a flexible fiber optical cable assembly (16 and 26), the fiber optical cable assembly including a first optical fiber (16) having a proximal end and a distal end, the first optical fiber (16) being adapted for transmitting optical radiation incident on the proximal end to the distal end; an optical source (38), including means for generating a beam of optical radiation directed to the proximal end of the first optical fiber (16); including: an electron source (52) for emitting electrons in

response to optical radiation transmitted to the distal end; and a target element (54), including at least one radiation emissive material adapted to generate therapeutic radiation (20) in response to incident electrons from the electron source (52); means (40) for providing an accelerating voltage between the electron source (52) and the target element (54) so as to establish an accelerating electric field which acts to accelerate electrons emitted from the electron source (52) toward the target element (54); and an in situ radiation detecting system (22) for monitoring an amount of the therapeutic radiation generated by the target element (54), the radiation detecting system (22) including: a second optical fiber (26), the second optical fiber (26) being formed of a scintillating material, the second optical fiber (26) being disposed outside the radiation generator assembly and the fiber optical cable assembly and along a path of the therapeutic radiation generated by the target element (54), the second optical fiber (26) being adapted to emit light in response to incident therapeutic radiation generated by the target element; a photodetector (46) in optical communication with the second optical fiber (26) for providing a signal indicative of the amount of therapeutic radiation that is incident on the second optical fiber 926); and a feedback controller (36) responsive to the indicative signal for calculating a cumulative dosage of the emitted therapeutic radiation and for controlling the intensity and duration of the therapeutic radiation (column 5; line 57 – column 8; line 58).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 19-23, 27-30, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinar et al. (US Patent 6,320,935 B1).

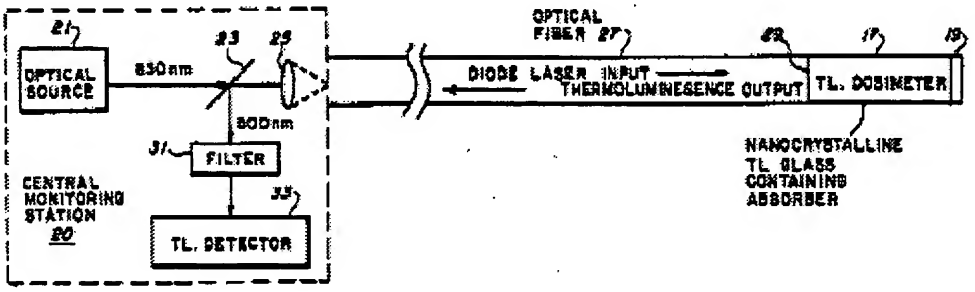
With respect to claims 19-21, Shinar teaches that scintillator can be made from any appropriate material with many modification and variations (column 10; lines 38-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the scintillator made from: a crystalline material; or material selected from the group consisting of sodium-iodide, cesium-iodide, bismuth-germinate, cesiumfluoride, ZnS, YAP:Ce (yittrium aluminum perovskite), terbium doped glass fiber; or material selected from the group consisting of glass, terbium doped glass fiber, and polymers, since it has been held that to be within the general skill of a worker in the art to select a known material on the bases its suitability for the intended use. In re Leshin, 125 USPQ 416.

With respect to claims 22,23 and 27-30 Shinar teaches that the electron source can comprise any appropriate configurations and materials with many modification and variations (column 3; lines 40-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the electron source includes a photocathode having a photosensitive surface and having a thermionic cathode having an electron-emissive surface and adapted to emit electrons since it has been held that to be within the general skill of a worker in the art to select a known material on the bases its suitability for the intended use. In re Leshin, 125 USPQ 416.

With respect to claim 37, Shiar fails to disclose LED (light emitting diode) as an optical source. Since LED is well known light source in the X-ray art, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide LED as an alternative light source for the therapeutic apparatus of Shinar.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shinar et al. (US Patent 6,320,935 B1) in view of Huston et al. (US Patent 5,606,163).

8. With respect to claim 35, Shinar generally shows all that is claimed except that the probe assembly including a fiber optic cable for transmitting optical radiation incident on the proximal end to the distal end and a detector (46) has optical communication through a same fiber optic cable. Huston teaches monitoring of radiation doses (X-ray and gamma radiation) in a patient (40) undergoing radiation therapy (Fig.7) with fiber optic components, wherein a detector (33) has optical communication through a same optical fiber (27) as a laser power (21) delivery fiber (27)(Fig.5).



Further an optical system comprises dichroic beam splitter (23) and filter (31) for selectively directing light to detector (33) and separating ambient visible light from optical radiation generated by the optical source (21) (column 5; lines 6-21).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ teaching of the in vivo monitoring of radiation exposure in the human body via fiber catheterization of Huston with the therapeutic radiation source of Shinar, in order to provide delivering and monitoring radiation with a single fiber optical cable to improve comfort and the effectiveness of radiation treatment with more precise control of radiation doses and help reducing collateral damage to healthy tissues.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irakli Kiknadze whose telephone number is (703) 305-6464. The examiner can normally be reached on M-F(8:30-5:00).

if attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (703) 308-4858. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

Irakli Kiknadze
August 7, 2003

EDWARD J. GLICK
Supervisory Patent EXAMINER
TECHNOLOGY CENTER 2800